K951902

Reynolds Medical Ltd.
510(k) Submission
Pathfinder 700 Holter Analyzer

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510(k) Summary

(a) Basic Data

(1) Submitter Information

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(2) Names of Device

Proprietary Name: Pathfinder 700 Holter Analyzer
Common/Usual Name: Holter analyzer
Classification Name: Arrhythmia Detector and Alarm

(3) Predicate Devices:

The principal predicate device is the Reynolds Pathfinder 3, which received marketing permission from the FDA under K871344 on October 20, 1987. The principal modification of the Pathfinder 700 is the use of modern, high-speed, digital technology.

Other predicate devices are the DelMar 263 (a PC-based analyzer, and the Zymed 1510 (also a stand-alone analyzer). Comparisons of the Pathfinder to these devices are in the Comparison section.

(4) Description of the Device

I. Introduction

The Pathfinder 700 Holter ECG analyzer is a high-speed Holter cassette analyzer capable of analyzing tapes recorded at 1.47 mm/second and 1.0 mm/second as well as solid-state recorders such as the Reynolds eRAM and the Braemar DL700. It is a successor to the Reynolds Pathfinder 3 analyzer, marketing of which has been approved by the FDA under 510(k) number K871344. The unit features arrhythmia analysis, ST deviation analysis, pacemaker beat detection, and determination of beat types, in both an automatic and interactive mode. The system uses an icon-based, mouse-controlled, Graphical User Interface ("GUI"), visually

similar to those found on the well-known Apple and Windows operating systems. Analysis is performed at 1000 times the recording speed, obtained by using parallel computations and a 188 megabyte random-access memory, in addition to a 1000 megabyte hard disk. Thus, a 24 hour Holter tape can be analyzed in approximately 1.5 minutes. A 486 motherboard is used to provide disk control and keyboard/mouse interfacing, while the analysis sections use parallel computing, based on the T400 and T425 transputers, a computer element which forms the basis of many parallel computing systems. The Pathfinder system is mouse-controlled, and uses a cathode-ray tube display and keyboard. The analysis is based on the Neilson principle or algorithm, which have been used in all previous Reynolds analyzers, and which have received 510(k) approval. The basic principles of the analysis are the same as those used previously by Reynolds; the new features of this system lie principally in its new electronic features, which have led to re-programming the equations and analysis principles.

II. Description of System

Physically, the analyzer computer is in a "tower" cabinet, to which are connected the keyboard, the mouse, the cathode-ray tube display, a laser printer. The tape reader is an integral part of the cabinet.

An optical disk accessory for archival storage is also offered. This option, which must be installed by Reynolds personnel, plays no role in the analysis or the operation of the program as is the solid state recorder interface.

The heart of the system, responsible for all Holter analysis, is the transputer data processing components. The transputer network communicates to peripherals by means of a 486 motherboard which gives it access to the hard disk and the keyboard. The tape reader, 188 megabyte RAM memory, video display, and laser printer communicate directly with the transputer components. The 486 motherboard boots the transputer network (including loading the individual RAMs with program) and then acts as a slave input/output processor for the keyboard, disk, mouse, and network services. It also monitors the "error" line from the transputer hardware and resets it if an error occurs. Network options are also available for archival storage.

The basic element of the parallel computer system is the transputer (derived from TRANSistor and comPUTER). The Pathfinder 700 uses mainly the T400 and T425 transputers (27 in all). Each of these devices have the basic capacity of

two INTEL 80386 chips (20 MHz), and each has internal memory. Basically, the transputer is an independent computing element (with the power of a motherboard chip with memory) which has links to other transputers, each of which has its own memory for computation and programming. Thus, they can each carry on independent computations. In addition, the transputers have internal timing circuits.

While this overview cannot give a detailed description of how parallel computing works, the following presents the general idea for a Holter monitor. The tape or solid state reader transfers the electrocardiogram to RAM, and the data in RAM is immediately analyzed by the parallel system while the tape-reading process is going on. The criteria for the analysis are set by the user, as will be explained later. The ECG data is also displayed and (if desired) printed and stored on disk. The results of the analysis are also stored in results storage (RAM), displayed, and printed and/or stored on disk. The mode of display can be selected by the user. However, since the entire operation of (tape reading > analysis > storage) takes only 90 seconds, the user is in general unaware of this underlying process. If the user has selected the "Automatic" mode, the results display and print-out can proceed after the 90 seconds. If "Interactive" mode is desired, the screens start showing intermediate results very rapidly, but the user is basically unaware of the fact that the entire analysis has probably already been completed.

III. General Program Flow

This section will present a brief description of the general program flow as seen by the operator. Note that this section does not describe the actual internal workings of the analyzer.

When the power is turned on after a boot period, the operator first sees a "basic display screen."

The basic display screen has a menu bar at the top, a representation of the ECG section currently being analyzed in the center, and an expanded section of the ECG at the bottom. This expanded ECG is in a rectangle called the "Highlight Box," and is used for selecting segments of the ECG during interactive analysis. The analysis criteria, scale factors, etc., can be changed by the operator, as explained in the instruction manual. The section marked "mouse buttons" shows the functions of the buttons on the mouse, which may change during various parts of the analysis.

The first menu to be selected would be "Start Analysis," which resets all adjustable parameters to "power-up" status and clears the memories, including patient details. The parameters can then be changed by means of "Control Analysis," which sets various values to be used in the analysis: for example, sensitivity, criteria for various tests, the number of channels on the tape, and whether automatic or interactive analysis is desired. This can only be set through "START ANALYSIS." Since parameters are rarely changed for different patients, the values of these parameters may be stored so that they become the "power-up" parameters. However, parameters can be changed after starting the tape and the initial analysis with only a slight loss in time, since the procedure is so rapid. In interactive analysis, the operator is presented with each event or complex (as selected by the operator) in the sequence indicated, accompanied by the diagnosis performed by the analysis. The operator then has the choice of accepting or changing these diagnoses. The operator can always enter interactive analysis at any time. If the criteria are not to be changed for succeeding tapes, the set-up can be saved to disk and it will be unnecessary to enter this menu for succeeding tapes.

The "Display Menu" controls the nature of the various displays as the analysis proceeds. For an automatic analysis, these displays are unnecessary, but for an interactive analysis, the operator can regulate the displays to facilitate the interactive process.

When "Start Analysis" is selected, menus appear to set up the particular analysis to be performed, including the type of recorder, the analysis type (automatic or interactive), options for printing the report, and the start time of the analysis. "Analyze" starts the analysis itself.

The analysis performed is the same for "automatic" and "interactive" modes, and, as noted above, the analysis is completed in about 90 seconds. In automatic mode, the report prints the first analysis "as is." In interactive mode, the operator can either change the classifications of arrhythmias proposed by the analysis algorithm, or can define new morphologies to be identified by the system.

The "Recorder Type" menu lists a large number of the most common recorders, as well as "generic" recorders. The system will automatically adjust to the recording speed of the recorder selected (1.0 mm/sec., 1.47 mm./sec or others) from the menu, as well as special formats which may be used.

After the analysis, the "Report" menu can be used to control whether the report is printed or stored, its language (English or other), its format, the sequence of the events in the report, and the sections to be included. Again, if all tapes are to have the same report choices, this section does not have to be changed for each analysis.

The overall flow is the following: After the initial selection of parameters and options, the system enters either automatic or interactive analysis. These analyses have an arrhythmia section, and an ST section. The ST section is optional, but the arrhythmia detection must always be selected. The unit then continues with the analyses, which are explained in more detail in the software section.

In operation, the tape reader supplies data to the Data Extraction unit, which also provides EMG (muscle noise) filtering. The data is then put into an ECG database. There are two identical channels for each channel of recorded data, plus a third channel to read the pacemaker channel. The data first goes through a "filter chain" to smooth the data, and then goes to a unit which determines the "trigger" position (where the unit "triggers" on a complex and a shape classification processor. The outputs are then combined and the arrhythmias are classified. The results go to the graphical interface for display. The Video Display Control is the path by which the user makes modifications in interactive analysis. The 486 motherboard is under the control of the DOS operating system. There is no "operating system" as such for the transputers.

(5) Intended Use

The Reynolds Pathfinder 700 Holter Analyzer is intended to be used to analyze magnetic tapes of ambulatory electrocardiograms made on compatible Holter Recorders. The system will detect various arrhythmias and will measure ST elevation or depression. The system acts in both an automatic mode (tape analyzed without operator intervention) and in an interactive mode (operator can intervene and affect analysis).

(6) Comparison with Predicate Devices

The Pathfinder 700 is substantially equivalent to the Reynolds Pathfinder 3, the DelMar 263, and the Zymed 1510, as noted previously.

(b) Performance Data

The Pathfinder 700 has been tested in comparison with the predicate devices, and also with standardized MIT and AHA tapes.

(1) Non-clinical tests

The Pathfinder 700 has been tested by independent laboratories, and it meets the requirements of IEC 950 1988 with amendments 1 and 2 and EN60590 1986 with amendments 1 and 2. Since the device is not patient connected, it is classed as office equipment. Electromagnetic compatibility tests have been done to EN 55022 level B.

These analyzers are now manufactured for sale in the United Kingdom and sold in more than ten countries around the world. The system has also received a French homologation.

The software has undergone extensive validation testing. The tests and results are in the Software section.

(2) Clinical Tests

The system has undergone a clinical test in which the analysis of the Pathfinder 700 has been compared to the analysis provided by a predicate device, the Pathfinder 3, and the Marquette 8000. In this test, the units under test analyzed standard AHA test tapes.

(3) Conclusion

The conclusions drawn from the non-clinical and clinical tests demonstrate that the device is as safe and effective, and performs as well or better than the legally marketed devices identified in paragraph (a)(3).